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Filed : May 3, 2001

### REMARKS

In the Restriction Requirement mailed May 27, 2004, the Examiner required restriction to one of four inventions:

- Group I (Claims 1, 4-8, 10, 11, 14-18, and 20-47), drawn to a method of treating the spine, classified in class 606, subclass 61;
- Group II (Claims 2, 12, and 48-60), drawn to a method of accessing the spine, classified in class 600, subclass 114;
- Group III (Claims 3 and 13), drawn to a therapeutic procedure, classified in class 604, subclass 3; or
- Group IV (Claims 10 and 19), drawn to a fixation device, classified in class 623, subclass 17.11.

Applicant elected, without traverse, the claims of Group I (Claims 1, 4-8, 10, 11, 14-18, and 20-47) for examination in the present application.

Prior to the foregoing amendments, Claims 1-60 were pending in the present application. In the Office Action mailed October 4, 2004, the Examiner withdrew from consideration Claims 2, 3, 9, 12, 13, 19, and 48-60, and rejected Claims 1, 4-8, 10, 11, 14-18, and 20-47.

#### Nonstatutory Double Patenting Rejections

The Examiner rejected Claims 1, 4-8, 10, 11, 14-18, and 20-47 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-86 of U.S. Patent No. 6,558,390 (Cragg).

The Examiner explained that a timely filed terminal disclaimer can be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground, provided the conflicting application or patent is shown to be commonly owned with the present application. See 37 C.F.R. § 1.130(b). Applicant has enclosed herewith a terminal disclaimer in compliance with 37 C.F.R. § 1.321(c) that disclaims the terminal part of the statutory term of any patent granted on the present application that would extend beyond the expiration date of U.S. Patent No. 6,558,390. Accordingly, Applicant respectfully requests that the double patenting rejection of Claims 1, 4-8, 10, 11, 14-18, and 20-47 be withdrawn.

#### Claim Rejections - 35 U.S.C. § 112, ¶ 2

The Examiner rejected Claims 4, 5, 7, 8, 10, 14, and 16-18 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter the Applicant regards as the invention. Specifically, the Examiner explained that these claims depend on a non-elected claim, and therefore are indefinite. For the purpose of examining Claims 4, 5, 7, 8, 10, 14, and 16-18, the Examiner considered these claims to depend on either Claim 1 or 11.

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Claims 4, 5, 7, 8, 10, 14, and 16-18 have been cancelled herein, without prejudice, for the procedural objective of simplifying the claims under examination and allowing the remaining claims to proceed toward issuance. Applicant reserves the right to pursue claims of the same or similar scope to those cancelled herein, in one or more continuing patent applications.

Claim Rejections - 35 U.S.C. § 102(e) - Claims 1, 4-8, 10, 11, 14-18, 40-42, and 45-57

The Examiner rejected Claims 1, 4-8, 10, 11, 14-18, 40-42, and 45-57 under 35 U.S.C. § 102(e) as being anticipated by Kuslich et al. (U.S. Patent No. 6,086,589). The Examiner asserts that Kuslich et al. discloses a method comprising identifying a site on the anterior or posterior surface of the sacrum (10), forming a lumen (22) from the site through the sacrum, through the sacrum, through a disc (18), and into at least one vertebrae, and performing a procedure using lumen (column 2, lines 27-67).

Applicant respectfully traverses these rejections and the Examiner's characterization of the cited reference. With respect to Claims 1 and 45, Applicant submits that Kuslich et al. fails to teach or suggest the unique combination of features recited by these claims. For example, Kuslich et al. fails to teach a method of treating the spine comprising identifying a site on the anterior surface of the sacrum, and forming a lumen from the site through the sacrum. Rather, Kuslich et al. discloses a method for posteriorly correcting spondylolisthesis that comprises drilling a linear hole (22) from the posterior side of the spine through two adjacent vertebrae (column 2, lines 27-53; column 4, lines 7-32; figures 4-7).

Claim 6, which depends from Claim 1, is believed to be patentable for the reasons stated above with respect to Claim 1, and because of the additional limitations set forth therein. Claims 46 and 47, which depend from Claim 45, are believed to be patentable for the reasons stated above with respect to Claim 45, and because of the additional limitations set forth therein. Accordingly, Applicant requests that the rejection of Claims 1, 6, and 45-47 be withdrawn.

With respect to Claim 11, Applicant submits that Kuslich et al. fails to teach or suggest the unique combination of features recited by this claim. For example, Kuslich et al. fails to teach a method of treating the spine comprising identifying a site on the posterior surface of the sacrum, and forming a nonlinear lumen through the site through the sacrum. Rather, Kuslich et al. discloses a method for posteriorly treating spondylolisthesis that comprises drilling a hole (22) posteriorly through two adjacent vertebrae, and then inserting a linear screw (10) into the drill

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hole (22). Kuslich et al. only discloses linear drill holes (22) that accommodate linear, elongated screws (10) (column 2, lines 27-53; column 4, lines 7-32; figures 4-7).

Claim 15, which depends from Claim 11, is believed to be patentable for the reasons stated above with respect to Claim 11, and because of the additional limitations set forth therein. Accordingly, Applicant requests that the rejection of Claims 11 and 15 be withdrawn.

Pending Claim 40 recites:

40. (Currently amended): A method of performing a procedure on the spine at a procedure site which is spaced apart from an access site, comprising the steps of:  
identifying an access site on the spine;  
inserting a tract sheath from a skin incision, through tissue, and to the access site;  
advancing a device through the skin incision, through the sheath, through the access site and into the spine;  
further advancing the device axially through at least one vertebrae and at least one disk to the procedure site; and  
performing a procedure at the procedure site;  
wherein the access site is on a healthy portion of the spine, and the procedure site is on an unhealthy or compromised portion of the spine.

Applicant submits that Kuslich et al. fails to teach or suggest the unique combination of features recited by Claim 40. For example, Kuslich et al. does not disclose a method that comprises inserting a tract sheath from a skin incision, through tissues, and to an access site. Also, Kuslich et al. does not disclose a method as recited above wherein the access site is on a healthy portion of the spine while the procedure site is on an unhealthy portion of the spine. Instead, Kuslich et al. discloses a method of treating spondyloisthesis posteriorly that comprises drilling a hole (22) through adjacent vertebrae and inserting a linear screw (10) into the hole (22).

Claims 41 and 42, which depend from Claim 40, are believed to be patentable for the reasons stated above with respect to Claim 40, and because of the additional limitations set forth therein. Accordingly, Applicant requests that the rejection of Claims 40-42 be withdrawn.

Claim Rejections - 35 U.S.C. §§ 102(e) and 103(a) - Claims 43 and 44

The Examiner rejected Claims 43 and 44 under § 102(e) as being anticipated by Helm et al. (U.S. Patent No. 6,805,697). The Examiner asserts that Helm et al. discloses a method comprising advancing a device (40) through an access pathway to the procedure site while the device has a first crossing profile, and enlarging the crossing profile of the device at the treatment site to perform the procedure (Figures 10-11).

Applicant respectfully traverses these rejections and the Examiner's characterization of the cited reference. Pending Claim 43 recites:

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43. (Currently amended): A method of performing a procedure from the inside of the spine, while minimizing the cross sectional area of an access pathway in the spine to ~~[[the]]~~ a procedure site, comprising the steps of:

inserting a tract sheath through a skin incision, through tissue, and to the access pathway, the access pathway beginning at the sacrum of the spine and extending axially into the lumbar spine;

advancing a device through [[an]] the sheath, through the access pathway in the spine to [[a]] the procedure site, while the device has a first, reduced crossing profile; and

enlarging the crossing profile of a portion of the device at the [[treatment]] procedure site to perform the procedure;

wherein the advancing step comprises advancing the device through at least one vertebrae and at least one disk.

Applicant submits that Helm et al. fails to teach or suggest the unique combination of features recited by Claim 43. For example, Helm et al. fails to teach or suggest a method that comprises inserting a tract sheath through a skin incision, through tissue, and to an access pathway which begins at the sacrum of the spine and extends axially into the lumbar spine. Helm et al. fails to teach or suggest a method that comprises advancing a device through the sheath, through the sacrum, and through the access pathway to the procedure site, while the device has a first, reduced crossing profile.

The Examiner also rejected Claims 43 and 44 under 35 U.S.C. § 103(a) as being unpatentable over Helm et al. The Examiner states that Helm et al. discloses all the limitations of these claims except for a passageway having a length 5 to 10 times its width. The Examiner asserts, however, that it would have been obvious to one of ordinary skill in the art to modify the device in Helm et al. so that the passageway has a length 5 to 10 times its width. Applicant respectfully traverses this rejection and the Examiner's characterization of the cited references.

In order to establish a *prima facie* case of obviousness for a claim, the prior art references must teach or suggest *all* the claim limitations. M.P.E.P. § 2143, at 2100-125 (Feb. 2003). Thus, to sustain the foregoing rejection of Claims 43 and 44, Helm et al. must identically teach or suggest every element of each Claim 43, arranged as in each Claim 43. Helm et al., however, neither teaches nor suggests a method comprising inserting a tract sheath through a skin incision, through tissue, and to the access pathway which begins at the sacrum and extends axially into the lumbar spine. Helm et al. teaches a method that comprises making small stab incisions in the back and drilling a hole laterally through cortical material on the outer surface of the pedicle of a vertebra (column 7, lines 60-63).

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Claim 44, which depends from Claim 43, is believed to be patentable for the reasons stated above with respect to Claim 43, and because of the additional limitations set forth therein. Accordingly, Applicant requests that the rejection of Claims 43 and 44 be withdrawn.

Claim Rejections - 35 U.S.C. § 103(a) - Claims 34 and 35

The Examiner rejected Claims 34 and 35 under 35 U.S.C. § 103(a) as being unpatentable over Helm et al. As with the rejection of Claims 43 and 44, the Examiner asserts that Helm et al. discloses all the limitations of Claims 34 and 35 except for a passageway having a length 5 to 10 times its width.

As explained above, in order to establish a *prima facie* case of obviousness, Helm et al. must teach or suggest *all* the claim limitations. M.P.E.P. § 2143, at 2100-125 (Feb. 2003). Pending Claim 34 recites:

34. (Currently amended): A method of treating the spine comprising creating a minimally invasive passageway ~~through tissue and into the spine, by inserting a tract sheath from a skin incision, through tissue, and through the sacrum of the spine,~~ wherein the passageway has a linear longitudinal axis and a length of at least about 5 times its width, and introducing at least one device through the passageway to treat the spine, wherein an extension of the axis extends through at least two intervertebral disks.

Applicant submits that Helm et al. fails to teach or suggest a method that comprises inserting a tract sheath linearly from a skin incision, through tissue, and through the sacrum of the spine.

Claim 35, which depends from Claim 34, is believed to be patentable for the reasons stated above with respect to Claim 34, and because of the additional limitations set forth therein. Accordingly, Applicant requests that the rejection of Claims 34 and 35 be withdrawn.

Claim Rejections - 35 U.S.C. § 103(a) - Claims 20-32

The Examiner rejected Claims 20-32 under 35 U.S.C. § 103(a) as being unpatentable over Kuslich et al. The Examiner states that Kuslich et al. does not teach a site within 5 mm from the coccyx, as recited in Claims 20-32. The Examiner, however, asserts that it would have been obvious to one of ordinary skill in the art to place the site at such a distance from the coccyx.

Pending Claim 20 recites:

20. (Currently amended): A method of treating the spine, comprising the steps of:  
 identifying a site on the skin of a patient, within about 5 cm from the coccyx;  
 providing a percutaneous access at the site and through tissue to the anterior surface of the  
[[sacrum;]] sacrum by inserting a tract sheath from the site, through a presacral space, and to the  
sacrum;  
 creating a lumen through the site, through the sheath, through the sacrum and at least one  
 lumbar vertebrae; and  
 using the lumen to perform a procedure.

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Applicant submits that Kuslich et al. fails to teach or suggest a method that comprises inserting a tract sheath from a site on the skin of the patient, through a presacral space, and to an anterior surface of the sacrum. Instead, Kuslich et al. discloses a method that comprises temporarily aligning the sacrum (12) and the L5 vertebra, and drilling a hole (22) posteriorly through the sacrum (column 2, lines 32-37).

Nothing in Kuslich et al. suggests introducing a sheath through a site on the skin which is within about 5 cm of the coccyx. To the contrary, Kuslich discloses a posterior approach to the sacrum, which is in excess of 5 cm from the coccyx. This reflects a fundamental difference between Kuslich, which discloses a posterior approach to the spine, and the present claimed invention, which enables an axial approach from a tissue entrance in the vicinity of the coccyx, onto an anterior surface of the sacrum.

Pending Claim 26 recites:

26. (Currently amended): A method of treating the spine at a treatment site which is spaced apart from an access site, comprising the steps of:  
identifying an access site on the spine;  
inserting a tract sheath from a skin incision, through tissue, and to the access site;  
advancing a device through the incision, through the sheath, through the access site and into the spine;  
further advancing the device axially through the spine for a distance across a treatment zone; and  
treating the spine in the treatment zone;  
wherein the distance is at least about 5 cm.

Applicant submits that Kuslich et al. fails to teach or suggest a method that comprises inserting a tract sheath from a skin incision, through tissue, and to an access site on the spine, then for an axial distance within the spine of at least about 5cm.

Claims 21-25, which depend from Claim 20, are believed to be patentable for the reasons stated above with respect to Claim 20, and because of the additional limitations set forth therein. Claims 27-33, which depend from Claim 26, are believed to be patentable for the reasons stated above with respect to Claim 26, and because of the additional limitations set forth therein. Accordingly, Applicant respectfully requests that the rejection of Claims 20-33 be withdrawn.

Claim Rejections - 35 U.S.C. § 103(a) - Claims 36-39

The Examiner rejected Claims 36-39 under 35 U.S.C. § 103(a) as being unpatentable over Helm et al. in view of Kuslich et al. The Examiner states that Helm et al. does not teach an anterior or posterior passageway and a fixation device, as recited in Claims 36-39. The Examiner

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asserts, however, that Kuslich et al. evidences the use of an anterior or posterior passageway and a fixation device to allow bone and fibrous through growth to stabilize the vertebrae. The Examiner concludes it would have been obvious to one of ordinary skill in the art to modify the method of Helm et al., in light of Kuslich et al., to provide a passageway and a fixation device, as recited in Claims 36-39.

Applicant respectfully traverses these rejections and the Examiner's characterization of the cited references. Claims 36-39, which depend from Claim 34, are believed to be patentable for the reasons stated above with respect to Claim 34, and because of the additional limitations set forth therein. Accordingly, Applicant respectfully requests that the rejection of Claims 36-39 be withdrawn.

In view of the foregoing, Applicant respectfully submits that the pending claims of the present application are in condition for allowance, and such action is earnestly solicited. If, however, any questions remain, the Examiner is cordially invited to contact the undersigned so that any such matter may be promptly resolved. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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